

Exhibit D

Attorney Docket No.: VASC 1020-1 US

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being sent by facsimile to:

Commissioner for Patents, Washington, DC 20231 at

(703) 308-2708 on ____ January 2003.

Signed:	
-	James F. Hann

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application

Inventors:

Bruce J Barclay and Kirti P. Kamdar

SC/Serial No.: 09/740,597

Confirm. No.: 3762

Filed:

19 December 2000

Title:

COVERED, COILED DRUG DELIVERY STENT

AND METHOD

PATENT APPLICATION

Group Art Unit: 3738

Examiner: Brian E.

Pellegrino

Customer No. 22470

Declaration of Kirti P. Kamdar

Commissioner for Patents Washington, DC 20231

Sir:

I, Kirti P. Kamdar, one of the joint inventors for this application, declare as follows.

I am Vice President, R&D for the assignee of this application, Vascular Architects, Inc. I was responsible for having an experimental study conducted to determine the extent and duration of nitric oxide (NO) release of the aSpire® covered stent containing a NO generator under dynamic flow conditions and am familiar with the procedures followed and the results obtained out this study. Twelve aSpire® covered stents (stent grafts) were divided into three groups. Group 1 consisted of 5 aSpire® covered stents containing a first NO-eluting mixture. Group 2 consisted of 5 aSpire® covered stents containing a second NO-eluting mixture. Group 3

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consisted of 2 control aSpire® covered stents. The two NO-eluting stent groups consisted of two different formulations of sodium nitroprusside (SNP), a NO donor, within a liquid silicone carrier. The testing proceeded as follows:

- 1. ePTFE tubing was placed onto 12 Nitinol stent frames;
- 2. the appropriate NO-eluting mixture was injected inside the ePTFE tubing for each of Groups 1 and 2; Group 3 containing no SNP or silicone;
- 3. the ends of ePTFE tubing were sealed providing 10 aSpire® covered stents (Groups 1 and 2) with NO-eluting mixtures sandwiched between two layers of ePTFE and surrounding the Nitinol stent frame;
- 4. each of the 12 aSpire® covered stents (12 mm x 5 cm) was placed into a separate testing chamber, each testing chamber connected to a separate circulatory system;
- 5. each testing chamber was then connected to a separate liquid reservoir containing phosphate buffered solution (PBS) to create a closed-loop circulating (100 ml/min.) test system;
- 6. each testing chamber, containing one of the 12 aSpire® covered stents, was then filled with the test liquid;
- 7. the test liquid was then circulated through each reservoir to permit the NO-eluting mixture to pass NO through ePTFE and into the test liquid of each testing chamber;
- 8. samples were taken periodically for 67 days to measure the amount of NO being released into each testing chamber; and
- 9. plots of NO vs. time were generated for Elution Data (the results of Groups 1 and 2 plotted separately) and T 1/2 (single plots for Group 1 and 2 plus a best-fit curve), attached as Exhibits E and F.

The results show that NO can be delivered for extended periods of time (more than 60 days) in physiologically effective amounts for the 12mm x 5cm aSpire® covered stent containing an NO-eluting mixture. The procedure for doing so is relatively straightforward and can be tailored to provide an improved or optimal delivery rate by, for example, adjusting the amount and concentration of the NO generator within the NO-eluting mixture.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Title 18, United States Code, § 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Kirti P. Kamdar

Date: 23 January 2003

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